

U.S. Serial No.: 10/021,294

Attorney Docket No.: CTCH-P01-014

**IN THE CLAIMS:**

1-4. (Cancelled)

5. (Previously Presented) A composition comprising:

a cyclodextrin-containing polymer,

a therapeutic agent, and

a complexing agent, comprising:

at least one guest moiety that forms an inclusion complex with a host moiety of said cyclodextrin-containing polymer, wherein the guest moiety is selected from adamantyl, naphthyl, cholesterol, and combinations thereof, and

at least one polymer portion that increases solubility and/or imparts stabilization relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone;

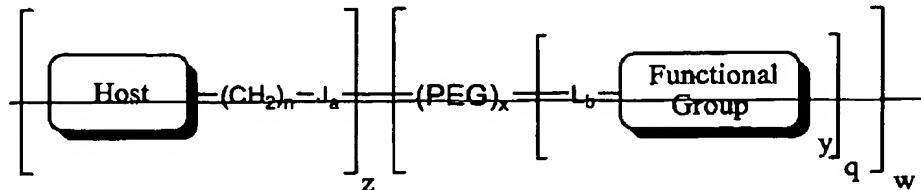
wherein the cyclodextrin-containing polymer, the therapeutic agent, and the complexing agent are separate molecules.

6. (Previously Presented) A composition of claim 5, wherein said therapeutic agent is selected from an antibiotic, a steroid, a polynucleotide, small molecule pharmaceutical, a virus, a plasmid, a peptide, a peptide fragment, a chelating agent, a biologically active macromolecule, and mixtures thereof.

7. (Original) A composition of claim 6, wherein said therapeutic agent is a polynucleotide.

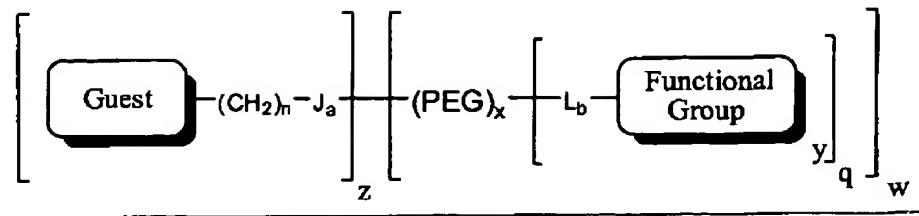
8-11. (Cancelled)

12. (Currently Amended) A composition of claim 5, wherein the complexing agent is a compound of the formula:

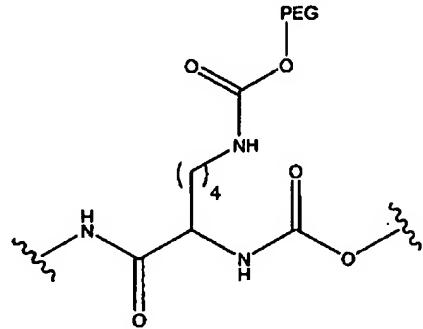


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wherein

J is  $-\text{NH}-$ ,  $-\text{C}(=\text{O})\text{NH}-\text{CH}_2-$ ,  $-\text{NH}-\text{C}(=\text{O})-(\text{CH}_2)_d-$ ,  $-\text{CH}_2\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-(\text{CH}_2)_e\text{O}-\text{P}(=\text{O})(\text{O}-$ 

, a peptide or polypeptide residue, or

 $-\text{NH}-(\text{C}(=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-(\text{C}(=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-$ ;

Y is an additional host-guest functionality;

R<sup>1</sup> is  $-(\text{CH}_2)\text{-CO}_2\text{H}$ , an ester or salt thereof; or  $-(\text{CH}_2)_a\text{-CONH}_2$ ;PEG is  $-\text{O}(\text{CH}_2\text{CH}_2\text{O})_z-$ , where z varies from 2 to 500;L is H,  $-\text{NH}-$ ,  $-\text{NH}-(\text{C}(=\text{O})-(\text{CH}_2)_e-(\text{C}(=\text{O})-\text{CH}_2-$ ,  $-\text{S}(=\text{O})_2\text{-HC=CH-}$ ,  $-\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-$ , or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

d ranges from 0 to 6;

e ranges from 1 to 6;

n ranges from 0 to 6;

q ranges from 1 to 5;

w ranges from 1 to 5;

y is 1; and

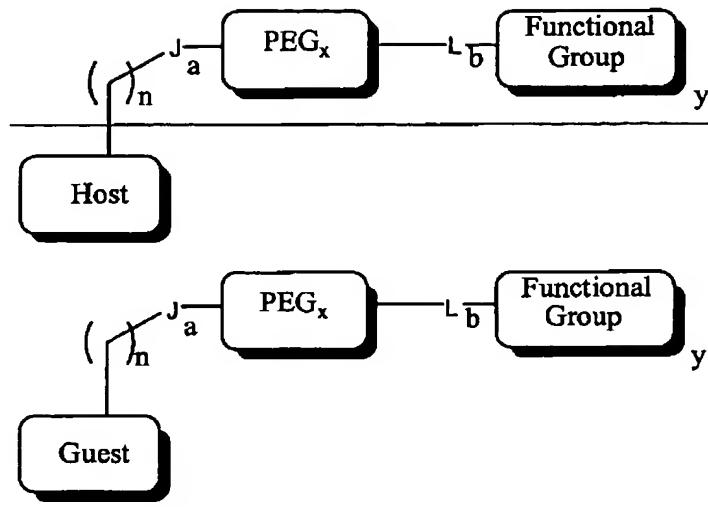
x is 0 or 1.

13. (Currently Amended) A composition of claim 5, wherein the complexing agent is a compound of the formula:

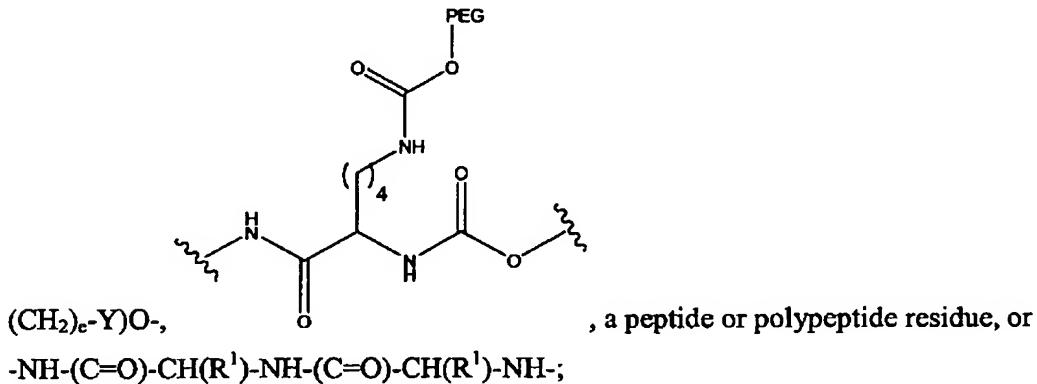
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wherein

J is -NH-, -C(=O)NH-CH<sub>2</sub><sub>d</sub>-, -NH-C(=O)-(CH<sub>2</sub>)<sub>d</sub>-, -CH<sub>2</sub>SS-, -C(=O)O-(CH<sub>2</sub>)<sub>c</sub>-O-P(=O)(O-

, a peptide or polypeptide residue, or

-NH-(C=O)-CH(R<sup>1</sup>)-NH-(C=O)-CH(R<sup>1</sup>)-NH-;

Y is an additional host-guest functionality;

R<sup>1</sup> is -(CH<sub>2</sub>)-CO<sub>2</sub>H, an ester or salt thereof; or -(CH<sub>2</sub>)<sub>a</sub>-CONH<sub>2</sub>;PEG is -O(CH<sub>2</sub>CH<sub>2</sub>O)<sub>z</sub>-, where z varies from 2 to 500;L is H, -NH, -NH-(C=O)-(CH<sub>2</sub>)<sub>e</sub>-(C=O)-CH<sub>2</sub>-, -S(=O)<sub>2</sub>-HC=CH-, -SS-, -C(=O)O-, or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

d ranges from 0 to 6;

e ranges from 1 to 6;

n ranges from 0 to 6;

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y is 1; and

x is 0 or 1.

14. (Previously Presented) A composition of claim 5, wherein the complexing agent further comprises a group selected from a ligand, a nuclear localization signal, an endosomal release peptide, an endosomal release polymer, or a membrane permeabilization agent.

15. (Previously Presented) A composition of claim 5, wherein the polymer portion increases the solubility of the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

16. (Previously Presented) A composition of claim 5, wherein the polymer portion stabilizes the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

17. (Previously Presented) A composition of claim 5, wherein the complexing agent further comprises a therapeutic agent reversibly bound to the complexing agent.

18. (Previously Presented) A composition of claim 5, wherein the complexing agent further comprises a spacer group.

19-22. (Cancelled)

23. (Previously Presented) A composition of claim 5, wherein at least one polymer portion of the complexing agent comprises PEG or derivatives thereof.

24-26. (Cancelled)

27. (Previously Presented) A composition of claim 5, wherein the cyclodextrin-containing polymer comprises one or more cyclodextrins in side chains of the cyclodextrin-containing polymer.

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28. (Previously Presented) A composition of claim 5, wherein the cyclodextrin-containing polymer comprises a linear cyclodextrin-containing polymer wherein cyclodextrin moieties are present in the backbone of the polymer.

29. (Cancelled)

30. (Previously Presented) A composition comprising:  
a cyclodextrin-containing polymer,  
a therapeutic agent, and  
a complexing agent, comprising:  
at least one functional group,  
at least one guest moiety that forms an inclusion complex with a host moiety of said cyclodextrin-containing polymer, wherein the guest moiety is selected from adamantyl, naphthyl, cholesterol, and combinations thereof, and  
at least one polymeric spacer group;  
wherein the cyclodextrin-containing polymer, the therapeutic agent, and the complexing agent are separate molecules.

31. (Previously Presented) A composition of claim 30, wherein said therapeutic agent is selected from an antibiotic, a steroid, a polynucleotide, small molecule pharmaceutical, a virus, a plasmid, a peptide, a peptide fragment, a chelating agent, a biologically active macromolecule, and mixtures thereof.

32. (Previously Presented) A composition of claim 31, wherein said therapeutic agent is a polynucleotide.

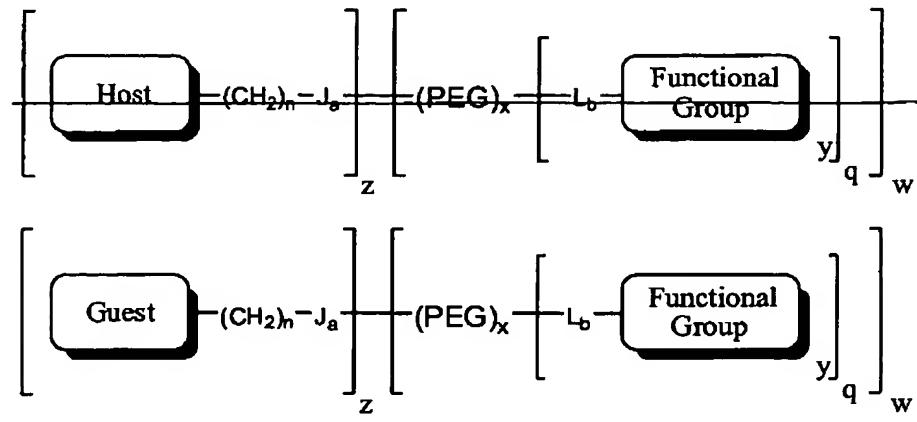
33. (Cancelled)

34. (Previously Presented) A composition of claim 30, wherein at least one spacer group of the complexing agent comprises PEG or derivatives thereof.

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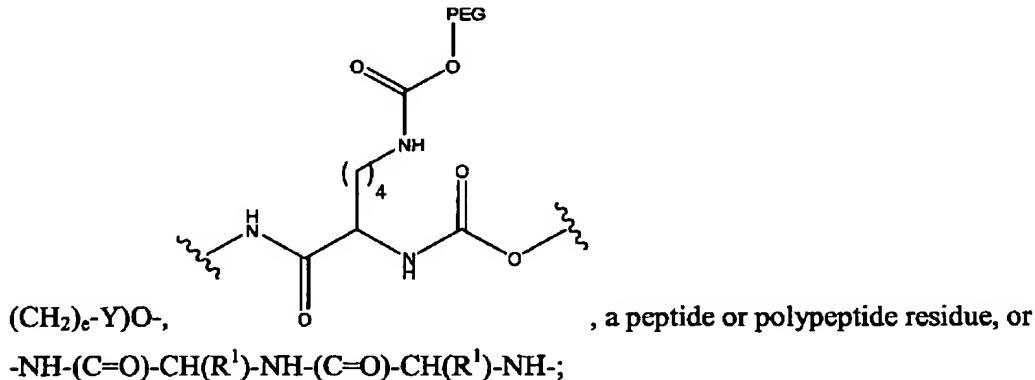
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35. (Currently Amended) A composition of claim 34, wherein the complexing agent is a compound of the formula:



wherein

J is -NH-, -C(=O)NH-CH<sub>2</sub>)<sub>d</sub>-, -NH-C(=O)-(CH<sub>2</sub>)<sub>d</sub>-, -CH<sub>2</sub>SS-, -C(=O)O-(CH<sub>2</sub>)<sub>e</sub>-O-P(=O)(O-



Y is an additional host-guest functionality;

R<sup>1</sup> is -(CH<sub>2</sub>)-CO<sub>2</sub>H, an ester or salt thereof; or -(CH<sub>2</sub>)<sub>a</sub>-CONH<sub>2</sub>;

PEG is -O(CH<sub>2</sub>CH<sub>2</sub>O)<sub>z</sub>-, where z varies from 2 to 500;

L is H, -NH, -NH-(C=O)-(CH<sub>2</sub>)<sub>e</sub>-(C=O)-CH<sub>2</sub>-, -S(=O)<sub>2</sub>-HC=CH-, -SS-, -C(=O)O-, or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

d ranges from 0 to 6;

e ranges from 1 to 6;

n ranges from 0 to 6;

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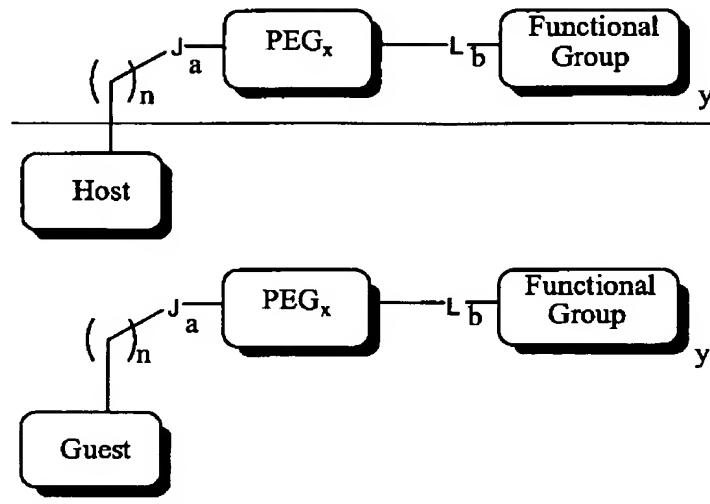
q ranges from 1 to 5;

w ranges from 1 to 5;

y is 1; and

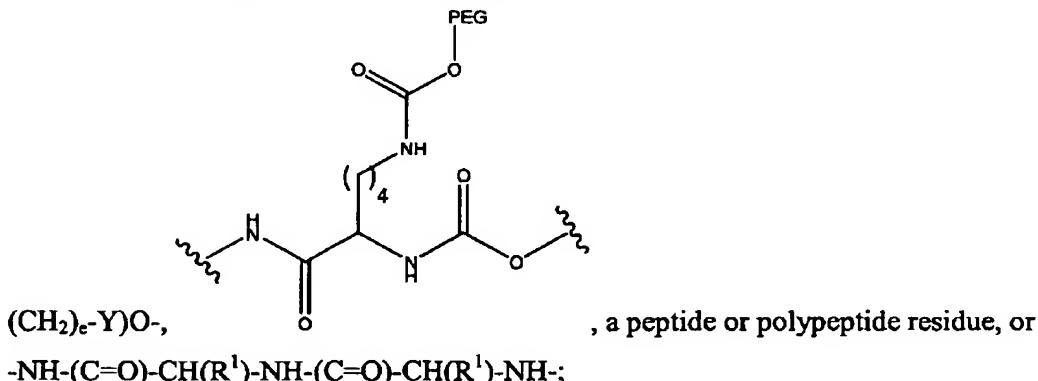
x is 1.

36. (Currently Amended) A composition of claim 34, wherein the complexing agent is a compound of the formula:



wherein

J is  $-\text{NH}-$ ,  $-\text{C}(=\text{O})\text{NH}-\text{CH}_2-$ ,  $-\text{NH}-\text{C}(=\text{O})-(\text{CH}_2)_d-$ ,  $-\text{CH}_2\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-(\text{CH}_2)_e-\text{O}-\text{P}(=\text{O})(\text{O}-$



Y is an additional host-guest functionality;

R<sup>1</sup> is  $-(\text{CH}_2)\text{CO}_2\text{H}$ , an ester or salt thereof, or  $-(\text{CH}_2)_k\text{CONH}_2$ ;

PEG is  $-\text{O}(\text{CH}_2\text{CH}_2\text{O})_z-$ , where z varies from 2 to 500;

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L is H, -NH, -NH-(C=O)-(CH<sub>2</sub>)<sub>e</sub>-(C=O)-CH<sub>2</sub>-, -S(=O)<sub>2</sub>-HC=CH-, -SS-, -C(=O)O-, or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

d ranges from 0 to 6;

e ranges from 1 to 6;

n ranges from 0 to 6;

y is 1; and

x is 1.

37. (Previously Presented) A composition of claim 30, wherein at least one functional group includes a group selected from a ligand, a nuclear localization signal, an endosomal release peptide, an endosomal release polymer, or a membrane permeabilization agent.

38. (Previously Presented) A composition of claim 30, wherein at least one functional group includes a moiety that increases the solubility of the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

39. (Previously Presented) A composition of claim 30, wherein at least one functional group includes a moiety that stabilizes the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

40. (Previously Presented) A composition of claim 30, wherein at least one functional group includes a therapeutic agent reversibly bound to the complexing agent.

41. (Previously Presented) A composition of claim 30, wherein the cyclodextrin-containing polymer comprises one or more cyclodextrins in side chains of the cyclodextrin-containing polymer.

42. (Previously Presented) A composition of claim 30, wherein the cyclodextrin-containing polymer comprises a linear cyclodextrin-containing polymer wherein cyclodextrin moieties are present in the backbone of the polymer.